K010450

SEP - 6 2001

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Submitted By: Lisa Hopkins
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, In 47402
(812) 339-2235
February 14, 2001

Device:

Trade Name:	Liver Tamponade Balloon
Proposed Classification Name:	Gastrointestinal Tube & Accessories

Predicate Device:

Zimmon Esophagogastric Balloon Tamponade Device	Marketed by Wilson-Cook Distributed by COOK INCORPORATED

Device Description

The Liver Tamponade Balloon consists of a silicone balloon mounted to a 16 Fr catheter. The balloon is long enough to cover a significant length of the liver in order to prevent the need for repeated repositioning until hemostasis is achieved. The diameter of the balloon is appropriate to tamponade a majority of the transfixing traumas while maintaining a somewhat uniform tubular shape throughout the length of the device.

Indications for Use

The Liver Tamponade Balloon is intended to tamponade bleeding from central, deep penetrating liver injuries not amenable to tractotomy or perihepatic packing. It is supplied sterile in peel-open packages and intended for one-time use.

Substantial Equivalence

The Liver Tamponade Balloon is similar in material and design and intended use to the commercially available Zimmon Esophagogastric Balloon Tamponade, marketed by Wilson-Cook. The Zimmon device was cleared under 510(k) D.C. #K900623.

K010450

Test Data

The Liver Tamponade Balloon was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests include:

- Balloon Burst Test
- Balloon Inflation/Deflation Test
- Analysis of Balloon Pressures and Diameters Test
- Evaluation of the Balloon to Shaft Bond Test
- Biocompatibility Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a liver tamponade balloon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2001

Ms. Lisa Hopkins
Regulatory Affairs Coordinator
Cook, Inc.
925 S. Curry Pike
P.O. Box 489
Bloomington, Indiana 47402

Re: K010450
Trade/Device Name: Liver Tamponade Balloon
Regulation Number: 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: NGU
Dated: June 7, 2001
Received: June 8, 2001

Dear Ms. Hopkins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

FOR Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Liver Tamponade Balloon

Indications for Use:

Intended to tamponade bleeding from central, deep penetrating liver injuries not amenable to tractotomy or perihepatic packing. It is provided sterile in peel-open packages and intended for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010450